Gedrag van nasaal toegediende tobramycine en colistine in het lichaam van patiënten met taaislijmziekte

Gepubliceerd: 08-05-2013 Laatst bijgewerkt: 15-05-2024

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28674

Bron
NTR

Verkorte titel
SPOEL study

Aandoening

Cystic Fibrosis

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: Lungfund Haga Teaching Hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- AUC (area under the curve);
- tmax (time to maximum concentration);
- Cmax (maximum plasma concentration);

- t1/2,el (terminal half-life);
- F (bioavailability).

Toelichting onderzoek

Achtergrond van het onderzoek

The sinonasal area of patients with Cystic Fibrosis (CF) can be a reservoir for P. aeruginosa from which cross-infection to the lungs may occur. Specific antimicrobial treatment for P. aeruginosa in the sinonasal area is not yet developed. Accurate treatment of this pathogen in the sinonasal area can prevent or postpone cross-infection to the lungs and consequently chronic lung infections. Studies of the pharmacokinetics of nasally administered tobramycin and colistin were never performed. Safety of this treatment has to be established before intervention studies on the effect of these drugs on clinical parameters are initiated. Systemic absorption can be used as surrogate parameter for safety.

Objective: To investigate the clinical pharmacokinetics of tobramycin and/or colistin after nasal administration.

Study design: Intervention study.

Study population: Patients of 18 or older with a confirmed diagnosis of Cystic Fibrosis attending the outpatient clinic of the Adult Cystic Fibrosis Center, Haga Teaching Hospital.

Intervention: Each patient irrigates the nose with tobramycin mixed with isotonic saline once, colistin dissolved in isotonic saline once and tobramycin and colistin together dissolved in isotonic saline once. Each subject visits the hospital six times. During three of those visits six venous blood samples are taken (in total 18 bloodsamples).

Onderzoeksopzet

Bloodsamples are collected at: t = 0, 0.5, 1, 2, 4, 6 hours after the nasal lavage.

Onderzoeksproduct en/of interventie

3 different types of nasal lavages: 1 = isotonic saline with tobramycin, 2 = isotonic saline with colistin, 3 = isotonic saline with tobramycin and colistin.
Each patient performs all three nasal lavages. No control group is necessary for this study. Patients perform each nasal lavage two times and for each nasal lavage the patient visits the hospital twice. The total duration of the study is 6 days.
For each type of nasal lavage 6 bloodsamples are taken, in which the concentration of the specific antibiotic is measured. With these data the farmacokinetics can be determined.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Confirmed diagnosis of Cystic Fibrosis based on genotyping or a positive sweat test;

- Age > 18 years;

- Intravenous course of tobramycin in the past, but within the age of 18 years, with a creatinine value measured during that same intravenous course of tobramycin.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Kidney dysfunction (defined as estimated Glomerular Filtration Rate of < 50 ml/min);

- Liver dysfunction (defined as at least one of the following enzymes ¡Ý 3 times the normal value; aspartate aminotransferase (ASAT), alanin aminotransferase (ALAT), Gamma-glutamyltransferase (gGT), lactate dehydrogenase (LD) and alkaline phosphatase (ALP);

- Intravenous treatment with aminoglycosides or polymyxins 48 hours;

- Acute pulmonary exacerbation ;

- Allergy or intolerance for aminoglycosides or polymyxins;

- Recurrent epistaxis;

- Recent surgery of ear, nose or sinuses (< 3 months before study entry);

- Participation in another clinical trial within 30 days prior to study entry.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2013
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-05-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38737
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3826
NTR-old	NTR4008
CCMO	NL43431.098.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38737

Resultaten

Samenvatting resultaten
N/A